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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/242,561 02/19/1999 YOSHIHIRO SATO 10235/4 1215

23838 7590 11/19/2001

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 11/19/2001

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,561

Applicant(s)

SATO, YOSHIHIRO

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,25,29,32-34 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,25,29,32-34 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 October 2001 has been entered.

2. This action is in response to papers filed 12 October 2001 in Paper No. 21 in which claims 21, 33 and 34 were amended and claims 36 and 40 were canceled. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 18 dated 24 July 2001 are withdrawn in view of the amendments. The arguments regarding the previous rejections have been considered but are deemed moot in view of the withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Currently claims 21, 22, 25, 29, 32-34 and 37-39 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 34 and 37-39 are indefinite in Claim 34 for the recitation "said contact surface" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 34 be amended to provide proper antecedent basis e.g. delete "said contact surface".

b. Claims 34 and 37-39 are indefinite in Claim 34 for the recitation "said protected minute droplet" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 34 be amended to provide proper antecedent basis e.g. delete "protected".

c. Claims 34 and 37-39 are indefinite in Claim 34 for the recitation "said produced minute droplet" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 34 be amended to provide proper antecedent basis e.g. delete "protected".

d. Claims 37 and 38 are both indefinite for the recitation "the contact surface" because the recitation lacks proper antecedent basis in Claim 34. It is suggested that Claims 37 and 38 be amended to provide proper antecedent basis e.g. replace "the" with "a".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21, 22, 25, 29, 32-34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent No. 6,143,496, filed 17 April 1997) in view of Blanchard et al. (Biosensors and Bioelectronics, 1996 11(6/7): 687-690).

Regarding Claim 21, Brown et al. teach a method for reducing evaporation of a minute droplet of an aqueous solution comprising: providing a planar substrate; providing an oily liquid layer (i.e. patches of sample retaining material selected from mineral oil, silicon oil and

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fluorinated oil, Column 9, lines 55-65); providing an aqueous solution immiscible with said oily layer; and retaining said minute droplet within said oily layer whereby said droplet is in contact with said substrate and said oily layer surrounds all surfaces of said droplet not in contact with said substrate (Column 27, lines 20-45 and Fig. 4) whereby evaporation is reduced (Column 6, lines 53-62). Brown et al. teach some embodiments wherein reagent droplets are introduced using ink jet techniques (Column 21, lines 8-10) but they are silent regarding delivery of droplet onto the planar substrate. However, ink jet delivery of aqueous solution onto planar substrates was well known in the art at the time the claimed invention was made as taught by Blanchard et al. who specifically teach ink jet delivery of minute aqueous droplets onto a substrate (page 688, left column last paragraph-right column) whereby reagent droplets are delivered accurately to small regions on the substrate allowing for high density deposit without mixing of adjacent droplets (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ink jet droplet delivery taught by Blanchard et al. to the method for reducing evaporation wherein isolated and discrete deposit is required as taught by Brown et al. (Column 6, line 59-62) and to shoot the droplets onto the substrate via ink jet technique for the expected benefit of precise and high density delivery of the droplets without risk of mixing adjacent droplets as taught by Blanchard et al. (Abstract).

Regarding Claim 22, Brown et al. teach the method wherein the planar substrate is water repellent i.e. glass (Column 11, lines 23-24 and 65-67).

Regarding Claim 25, Brown et al. teach the method wherein the oily liquid layer is selected from mineral oil, silicon oil and fluorinated oil, Column 9, lines 55-65).

Regarding Claim 29, Brown et al. teach the method further comprising a covering over said oily layer (Column 27, lines 20-32).

Regarding Claim 32, Brown et al. teach the method further comprising providing a second aqueous solution into said oily layer adjacent to said minute droplet i.e. a second

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droplet is placed adjacent to the first droplet on the array to provide a patterned array comprising a plurality of minute droplets (Column 16, lines 9-19).

Regarding Claim 33, Brown et al. teach a method for reducing evaporation of a minute droplet of an aqueous solution comprising: providing a planar substrate; providing an oily liquid layer (i.e. patches of sample retaining material selected from mineral oil, silicon oil and fluorinated oil, Column 9, lines 55-65); providing an aqueous solution immiscible with said oily layer; and retaining said minute droplet within said oily layer whereby said droplet is in contact with said substrate and said oily layer surrounds all surfaces of said droplet not in contact with said substrate (Column 27, lines 20-45 and Fig. 4) and a covering in contact with said minute droplet via the retaining material (Column 27, lines 20-32) whereby evaporation is reduced (Column 6, lines 53-62). Brown et al. teach some embodiments wherein reagent droplets are introduced using ink jet techniques (Column 21, lines 8-10) but they are silent regarding delivery of droplet onto the planar substrate. However, ink jet delivery of aqueous solution onto planar substrates was well known in the art at the time the claimed invention was made as taught by Blanchard et al. who specifically teach ink jet delivery of minute aqueous droplets onto a substrate (page 688, left column last paragraph-right column) whereby reagent droplets are delivered accurately to small regions on the substrate allowing for high density deposit without mixing of adjacent droplets (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ink jet droplet delivery taught by Blanchard et al. to the method for reducing evaporation wherein isolated and discrete deposit is required as taught by Brown et al. (Column 6, line 59-62) and to shoot the droplets onto the substrate via ink jet technique for the expected benefit of precise and high density delivery of the droplets without risk of mixing adjacent droplets as taught by Blanchard et al. (Abstract).

Regarding Claim 34, Brown et al. teach a method for conducting a PCR reaction in a minute droplet of an aqueous solution comprising: providing a planar substrate; providing an

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oily liquid layer (i.e. patches of sample retaining material selected from mineral oil, silicon oil and fluorinated oil, Column 9, lines 55-65); providing an aqueous solution immiscible with said oily layer; and retaining said minute droplet within said oily layer whereby said droplet is in contact with said substrate and said oily layer surrounds all surfaces of said droplet not in contact with said substrate (Column 27, lines 20-45 and Fig. 4) and providing reactant to said droplet (i.e. PCR reaction mixture, Column 5, lines 22-35) whereby evaporation is reduced (Column 6, lines 53-62). Brown et al. teach some embodiments wherein reagent droplets are introduced using ink jet techniques (Column 21, lines 8-10) but they are silent regarding delivery of droplet onto the planar substrate. However, ink jet delivery of aqueous solution onto planar substrates was well known in the art at the time the claimed invention was made as taught by Blanchard et al. who specifically teach ink jet delivery of minute aqueous droplets onto a substrate (page 688, left column last paragraph-right column) whereby reagent droplets are delivered accurately to small regions on the substrate allowing for high density deposit without mixing of adjacent droplets (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ink jet droplet delivery taught by Blanchard et al. to the method for reducing evaporation wherein isolated and discrete deposit is required as taught by Brown et al. (Column 6, line 59-62) and to shoot the droplets onto the substrate via ink jet technique for the expected benefit of precise and high density delivery of the droplets without risk of mixing adjacent droplets as taught by Blanchard et al. (Abstract).

Regarding Claim 39, Brown et al. teach the method wherein the oily layer has a thickness of about 100 μ m i.e. the sample chamber containing the oily layer have a diameter of about 100 μ m and therefore the oily layer has a thickness of about 100 μ m or less (Column 24, lines 46-53)

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7. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent No. 6,143,496, filed 17 April 1997) in view of Blanchard et al. (Biosensors and Bioelectronics, 1996 11(6/7): 687-690) as applied to Claim 34 above and further in view of Sambrook et al. (Molecular Cloning: A laboratory Manual, 2nd, 1992, pages 9.47-9.48).

Regarding Claim 37 and 38, Brown et al. teach a method for conducting a PCR reaction in a minute droplet of an aqueous solution comprising: providing a planar substrate; providing an oily liquid layer (i.e. patches of sample retaining material selected from mineral oil, silicon oil and fluorinated oil, Column 9, lines 55-65); providing an aqueous solution immiscible with said oily layer; and retaining said minute droplet within said oily layer whereby said droplet is in contact with said substrate and said oily layer surrounds all surfaces of said droplet not in contact with said substrate (Column 27, lines 20-45 and Fig. 4) whereby evaporation is reduced (Column 6, lines 53-62) and they teach their PCR reaction mixture comprises and enzyme adsorption preventing agent (Claim 37) i.e. BSA (Claim 38) (Column 30, line 63-Column 31, line 6). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the PCR reaction mixture taught by Brown et al. to their method for conducting a PCR reaction in a minute droplet and to add BSA to the minute droplet to contact the planar substrate for the known benefits of BSA in PCR reactions i.e. blocks non-specific binding reactions and increases signal-to-noise ratios (Sambrook et al., page 9.47-9.48).

Conclusion


8. No claim is allowed.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
November 14, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600